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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,791	02/25/2004	Zhaoda Zhang	13498-010003	9031
26191	7590	02/09/2006		
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 02/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/786,791	ZHANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/18/05; 2/24/04; 10/15/04; 6/24/04; + 3/29/04
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23,27-33,56-65 and 68-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23,27-33,56-65 and 68-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/15/04; 6/24/04; 3/24/04; + 3/24/04</u>                                 | 6) <input type="checkbox"/> Other: _____                                    |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 2/24/04 wherein the specification was amended; claim 2 was amended; and claims 24-26, 34-55, 66, and 67 were canceled.

**Note:** Claims 1-23, 27-33, 56-65, and 68-77 are pending.

## **RESPONSE TO APPLICANT'S ELECTION**

2. Applicant's election with traverse of Group I filed 11/18/05 is acknowledged. The traversal is on the grounds that the instant invention is a divisional of 10/209,183 (now abandoned) and the preliminary amendment filed 2/25/04 (in the instant invention) was with the intent of pursuing a restricted group identified by the Examiner in the parent application. Thus, Applicant stated in their preliminary amendment that claims 1-23, 27-33, 56-65, and 68-77 correspond to Restriction Group 2 directed to a method of making an MRI agent using a peptide and the linker subunit moiety (that is found in claim 2 of the instant invention) as set forth in the restriction requirement in the parent application. In addition the preliminary amendment indicated that Applicant was also electing that the species of Structure 36 for initial prosecution and that claims 1-3, 5-8, 11, 13-15, 17, 19-22, 27, 29-33, 56-65, 68, and 70-76 read on the elected invention. This is found persuasive. Hence, the restriction has been modified to that of the parent application. As a result, Structure 36 is the elected species and Group 2 has been modified to be consistent with that of the parent (a method of making an MRI agent using a peptide and the linker subunit that is found in claim 2 of the instant invention)

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Hence, the restriction requirement is deemed proper and is therefore made FINAL.

**Note:** Initially, Applicant's elected species (the species of Structure 36) was searched. However, since no prior art was found which could be used to reject the claims, the search was expanded to the linker subunit as set forth in claim 2 in combination with any peptide. The search was not further extended because prior art was found which could be used to reject the claims of the instant invention.

### STATUTORY DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1, 3-23, 27-33, 56-65, and 68-77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-23, 27-33, 56-65, and

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68-77 of copending Application No. 11/098,665. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

## **OBVIOUSNESS-TYPE DOUBLE PATENTING**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 11/098,665. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims disclose the linker subunit moiety as set forth in the instant invention. The claims differ in that claim 2 of 11/098,665 disclose various linker subunits whereas in claim 2 of the instant invention only one linker subunit moiety is present. Thus, a skilled practitioner in the art would recognize that both applications disclose the same linker subunit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## 112 REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13, 15, 20, 29-31, 57, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13: The claim as written is ambiguous because one cannot readily ascertain what is being claimed. In particular, it is unclear what substituents Applicant is claiming to be compatible with the instant invention for the variable R. In other words, the phrase, R...a negative charge and a negative charge precursor' is vague and indefinite.

Claims 15, 29, 30, 57: The claim as written is ambiguous because it is unclear what 'precursor chelate moiety' and 'plurality of carboxylate precursor groups' Applicant is claiming to be compatible with the instant invention.

Claims 20 and 58: The claim is ambiguous because it is unclear what 'carboxylate precursor groups' Applicant is claiming that are compatible with the instant invention.

Claim 31: The claim as written is ambiguous because it is unclear what species are encompassed by Applicant's phrase 'carboxylate precursors'. In particular, it is unclear what species Applicant is claiming that are compatible with the instant invention.

## **103 REJECTION**

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 5-8, 15, 20-23, 27-33, 56-64, 68, and 70-77 are rejected under 35 U.S.C. 103(a) as being unpatentable Carpenter et al (US Patent No. 6,656,448)

**Carpenter et al** disclose diagnostic agent comprising a diagnostic metal, one to 10 targeting moieties, a chelator, and optionally, a linking group (see entire document, especially, abstract; column 5, lines 19-29). In addition, Carpenter et al discloses the following. (1) The compositions of their invention may be used as magnetic resonance imaging contrast agents (column 4, lines 16-24). (2) The diagnostic metal may be selected from Gd(III), Dy(III), Fe(III), and Mn(II) (column 21, lines 65-68). (3) Various diagnostic agents are disclosed which comprise the linker subunit as set forth in claim 2 of the instant invention (column 35, line 66; columns 64-66, Example 2; columns 71, Example 6; column 74, Example 8; Example 76, Example 10; and column 77, Example 12). (4) A stabilization aid may be added to the compositions. The stabilization aid is a component that is added to the metallopharmaceutical or diagnostic kit either to stabilize the metallopharmaceutical or to prolong the shelf life of the kit prior to its use (column 43, lines 52-59). (5) The coupling of two amino acid derivatives, an amino acid and a peptide, a polypeptide or peptidomimetic, or two peptides, polypeptides, or peptidomimetic fragments may be performed using standard coupling procedures such as active ester (i.e., N-hydroxysuccinic imido ester) or the addition of hydroxybenzotriazole (column 51, lines 11-24). (6) Various functional groups may be present in the composition. Possible functional groups include hydroxyl, carboxyl, carboxamide, nitro, ether, ketone, amino, ammonium, sulfonate, sulfonamide, phosphonate, and phosphonamide (column 57, lines 5-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate methods of making magnetic resonance imaging

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agents as set forth in independent claims 1, 27, 56, 68, 69, and 70 having the linker subunit moiety as set forth in independent claim 2 because both Applicant and Carpenter et al disclose methods of making peptide compositions and uses thereof wherein the linker subunit is that of claim 2 of the instant invention. In addition, it would be obvious to a skilled practitioner in the art that Carpenter et al is directed to a method of altering the stability of a peptide because in column 43, lines 52-60, it is disclosed that a stabilization aid may be added to the composition to either stabilize the metallopharmaceutical or to prolong the shelf-life of the kit.

#### **SPECIFICATION**

11. The disclosure is objected to because of the following informalities: the cross reference to related application number 10/209,172 does not set forth whether the instant application is a DIV, CON, or CIP of 10/209,172.

Appropriate correction is required.

#### **CLAIM OBJECTIONS**

12. Claims 11, 14, 16, 17, 19, and 65 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **COMMENTS/NOTES**

13. It should be noted that prior art has not been cited against all of Applicant's claims. The claims wherein no prior art rejections have been set forth are distinguished

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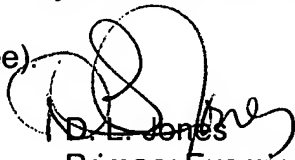
over the prior art of record because the prior art neither anticipates nor renders obvious the limitations found in the dependent claims. However, Applicant MUST address and overcome the double patenting and 112 rejections above.

14. Applicant is respectfully requested to insert the term 'and' between the structure of claims 17 and 19.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1618

February 3, 2006